

acquisition cost and AWP), physicians have reaped substantial profits.” (IAWP051149-52) (Highly Confidential).

439. Immunex, in a conscious effort to increase the spread for providers and intermediaries, changed its AWP and marketing practices accordingly. In a February 21, 1997 internal memo discussing reimbursement on its products, in pertinent part, Immunex stated:

The following are the reimbursement schema for Leukine, Novantrone, Thioplex and Leucovorin:

Here’s the way it works [for Leukine] – the Red Book Price (AWP) for our 250 mcg is \$117.79 and \$221.71. However, payors take the \$117.79 and divide it by 5, now that we bill per 50 mcg increments. This is equal to \$23.56 per 50 mcg, hence reimbursement on a 500 mcg vial is \$235.60. We need to take into account that in some AOR markets they get AWP or AWP plus a percentage, in others, depending on the makeup of the patient population, they may only get the 80% Medicare allowable (\$188.48). So here’s what the spread looks like:

\$235.60 (AWP)	\$188.48 (80% Medicare allowable)
- <u>\$112.06</u> (AOR contract price)	- <u>\$112.06</u>
+ <u>\$123.54</u> per 500 mcg vial (110% spread)	\$76.42 (68% spread)

(IAWP008528) (Highly Confidential) (emphasis in original).

440. Immunex performed an analysis of competitive AWP pricing (IAWP003407-13) (Highly Confidential) and established a “Reimbursement Hotline” for a number of its products (IAWP016686-88) (Highly Confidential).

441. Immunex, through its employees and agents, also provided free samples of its drugs to customers. (IAWP005418) (Highly Confidential) The free samples would be used to offset the total cost associated with purchases of its drugs, thereby increasing the spread, while also concealing the actual cost of the drug from Plaintiffs and the Class.

## 5. Specific Immunex AWP Documented by the DOJ

442. In a report published by the DHHS (the “DHHS Report”), the DOJ documented at least 7 instances where the published AWP for various dosages of 2 drugs manufactured by

Immunex were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the 2 drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Immunex in the 2001 *Red Book*.

<b>Drug</b>	<b>2001 <i>Red Book</i> AWP</b>	<b>DOJ Determined Actual AWP</b>	<b>Difference</b>	<b>Percentage Spread</b>
Leucovorin Calcium	\$137.94	\$14.58	\$123.36	846%
Methotrexate Sodium	\$20.48	\$7.10	\$13.38	188%

(P006299-P006316).

443. In a report published by DHHS in 1997, the Department undertook an analysis of the twenty drug codes that represented the largest dollar outlays to the Medicare Program and compared Medicare's payments with the prices available to the physician and supplier communities. For mitoxantrone hydrochloride, sold by Immunex under the brand name Novantrone, the DHHS found that Medicare paid \$172.81, while the actual average wholesale price was \$142.40, resulting in a spread of 21.36%. "Excessive Medicare Payments for Prescription Drugs" (Dec. 1997).

#### **6. Inflated AWP's From Immunex Price Lists**

444. In response to government subpoenas, Immunex produced numerous price lists setting forth spreads between AWP's and prices offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Immunex has consistently offered drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers.

445. As set forth above, Immunex's scheme to inflate its reported AWP's and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

## 7. Immunex Concealed Its AWP Manipulation

446. Immunex deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread. For example, under the guise of “simplifying” its product listings, on June 3, 1994, Immunex instructed the *Red Book* to “delete all references to Direct Price for all Immunex products, effective immediately” and confirmed that “only AWP (Average Wholesale Price) w[ould] be listed for [its] products[.]” (IAWP016524) (Highly Confidential). Immunex effectively hid the AWP spread from Plaintiffs and the Class.

## N. The Johnson & Johnson Group (J&J, Centocor and Ortho)

447. The Johnson & Johnson Group engages in an organization-wide and deliberate scheme to inflate AWP. The Johnson & Johnson Group has stated fraudulent AWP for all or almost all of its drugs, including those set forth below. The specific drugs of the Johnson & Johnson Group for which relief is sought in this case are set forth in Appendix A, and are set forth below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
JOHNSON & JOHNSON GROUP (J&J, Janssen, McNeil, Ortho and	Aciphex	rabeprazole sodium	Gastric Acid Pump Inhibitor (Gastrointestinal Agent) Used in the treatment of gastroesophageal reflux disease and duodenal ulcers
Centocor)	Bicitra	sodium citrate & citric acid	Alkalizer Used in the prevention of kidney stones
	Duragesic	fentanyl	Analgesic Used in the treatment of chronic pain
	Elmiron	pentosan polysulfate sodium	Anti-Inflammatory Agent Used for relief of pain associated with interstitial cystitis
	Erycette	erythromycin	Antiacne Agent; Antibacterial Agent Used to help control acne
	Flexeril	cyclobenzaprine	Skeletal Muscle Relaxant (Analgesic) Used in the treatment of muscle spasm associated with musculoskeletal conditions
	Floxin	ofloxacin	Antibacterial Agent Used in the treatment of pneumonia, bronchitis, gonorrhea and certain other infections

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Grifulvin	griseofulvin microsize	Antifungal Agent Used to treat fungus infections of the skin, hair, fingernails, and toenails
	Haldol	haloperidol lactate	Antiemetic (Gastrointestinal Agent); Antipsychotic (Psychotherapeutic Agent) Used to treat nervous, mental, and emotional conditions
	Haldol Decanoate	haloperidol decanoate	Antiemetic (Gastrointestinal Agent); Antipsychotic (Psychotherapeutic Agent) Used to treat nervous, mental, and emotional conditions
	Levaquin	levofloxacin	Antibacterial Agent Used to treat bacterial infections in many different parts of the body
	Monistat	miconazole nitrate	Antifungal Agent Used in the treatment of yeast infections
	Mycelex	clotrimazole	Antifungal Agent Used in the treatment of candidiasis and tinea versicolor
	Pancrease	amylase-lipase- protease	Digestant; Enzyme, Pancreatic (Gastrointestinal Agent) Used in the treatment of gastrointestinal orders
	Parafon Fort	chlorzoxazone	Skeletal Muscle Relaxant (Analgesic) Used to relax certain muscles and relieve the pain and discomfort caused by strains, sprains, or other injuries to muscles
	Polycitra	potassium & sodium citrates w/ citric acid	Alkalizer Used in the prevention of kidney stones
	Procrit	epoetin alfa	Antianemic Used in the treatment of anemia in HIV- infected, cancer or chronic renal failure patients
	Regranex	becaplermin	Biological Response Modifier Used in the treatment of diabetic neuropathic ulcers
	Remicade	infliximab	Anti-Inflammatory Agent; Antirheumatic Agent Used to treat Crohn's disease and rheumatoid arthritis
	Reminyl	galantamine hydrobromide	Cholinesterase Inhibitor (Central Nervous System Agent) Used in the treatment of dementia of the Alzheimer's type

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Renova	tretinoin	Antiacne Agent Used for mitigation of fine wrinkles and other attributes of facial skin
	Retin-A	tretinoin	Antiacne Agent Used to treat acne
	Retin-A Micro	tretinoin microsphere	Antiacne Agent Used to treat acne
	Risperdal	risperidone	Antipsychotic Agent (Psychotherapeutic Agent) Used to treat the symptoms of psychotic disorders
	Spectazole	econazole nitrate	Antifungal Agent Used to treat infections caused by a fungus
	Sporanox	itraconazole	Antifungal Agent Used in the treatment of various fungal infections
	Terazol	terconazole vaginal	Antifungal Agent Used to treat yeast (fungus) infections of the vagina
	Testoderm	testosterone	Androgen; Antianemic Agent; Antineoplastic Used for replacement therapy in males with a deficiency or absence of testosterone
	Tolectin	tolmetin sodium	Antirheumatic Agent Used to relieve some symptoms caused by arthritis
	Topamax	topiramate	Anticonvulsant Used to help control some types of seizures in the treatment of epilepsy
	Tylox	acetaminophen w/ codeine	Analgesic Used to relieve pain.
	Tylenol with codeine		
	Ultracet	tramadol- acetaminophen	Analgesic Used to relieve pain
	Ultram	tramadol hcl	Analgesic Used for management of pain
	Urispas	flavoxate hydrochloride	Autonomic Nervous System Agent Used in the treatment of symptoms of various urologic disorders.
	Vascor	bepidril hcl	Antianginal Agent Used to relieve and control angina pectoris and hypertension

**1. The Johnson & Johnson Group Has Been the Target of Government Investigations**

448. In connection with its scheme to inflate AWP's, the Johnson & Johnson Group has been investigated by the General Accounting Office and the Office of the Attorney general for the Commonwealth of Massachusetts.

449. J&J's internal documents reveal that it was familiar with and understood how industry compendia defined and utilized AWP's. For example, in a rebate agreement between J&J and Merck-Medco Managed Care, Inc. dated December 19, 1996, the parties defined AWP as meaning "the average wholesale price as published in the most current version of either First Data Bank or the Red Book." (J&J000599) (Highly Confidential).

450. The Johnson & Johnson Group has engaged in an ongoing deliberate scheme to inflate AWP's and to market the spread to increase the sales of its products. In a report published by the GAO, federal investigations have documented fraudulently inflated AWP's reported for epoetin alpha (sold by J&J as Procrit). J&J is identified in various annual *Red Book* publications as one of two sources for epoetin alfa. The other source for epoetin alfa is Defendant Amgen.<sup>6</sup>

451. In September 2001, the GAO reported that epoetin alfa accounted for the second highest percentage of Medicare expenditures on drugs in 1999, accounting for 9.5% of spending for prescription drugs by Medicare in 1999 and for 3.4% of all Medicare allowed services. These massive federal expenditures for epoetin alfa, caused by the J&J Group and Amgen's AWP scheme as well as the inflated cost to Plaintiffs and members of the Class, are even more outrageous given the fact that the research and development of epoetin alfa was originally underwritten by grants from the federal government.<sup>7</sup>

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<sup>6</sup> Amgen markets epoetin alfa for use in the treatment of dialysis patients while the right to market epoetin alfa for all other uses is licensed to Defendant J&J.

<sup>7</sup> Epogen® and Procrit® are based on different uses of a patented process technology developed at Columbia University with support from grants from the NIH. Columbia licensed their technology to Amgen for Epogen® and to Johnson & Johnson for Procrit®. *NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers' Interests are Protected*, Department Of Health And Human Services National Institutes Of Health, July 2001.

452. By way of further example, the J&J Group has deliberately overstated and continues to overstate the AWP for Remicade®. The published AWP for Remicade® continued to increase each year during the class period. For example, the AWP was listed as \$611.33 for a 100 mg vial of Remicade® as of November 1999, and rose to \$665.65 when listed in the 2001 edition of the *Red Book*. At the same time, J&J deliberately marketed and promoted the sale of Remicade® to physicians based on the availability of inflated payments made by Medicare, assuring them that they would make a significant profit from the purchase of Remicade® as a result of the spread between the actual price to physicians and reimbursement based on the published AWP.

453. The J&J Group created promotional materials and worksheets to allow them to market the spread between the published AWP and the actual selling price to doctors. For example, a publication accessible through Defendants' web sites entitled "Office-Based Infusion Guide" demonstrates Defendants' aggressive marketing of this spread, specifically noting that, "[d]epending on reimbursement, office-based infusion may provide a financial impact to a physician's practice." Moreover, the "Financial Analysis" section of the guide includes a "REMICADE® (infliximab) Financial Impact Worksheet," which enables doctors see in actual dollars how much additional revenue the use of Remicade® would bring to their practice.

454. As set forth above, the J&J Group's scheme to inflate its reported AWP's and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

455. Set forth below in Table 1 are the contract prices (not already referenced above) included in a J&J contract price list (effective from April 1, 1997 through March 31, 1998) contained in a supply agreement with Managed Healthcare Associates, Inc. dated March 17, 1997 and the AWP published in the 1997 *Red Book*, and their associated AWP spread. (J&J000121-23) (Highly Confidential).



**Table 1**

<b>Drug</b>	<b>Contract Price</b>	<b>AWP</b>	<b>\$ Diff AWP</b>	<b>% Spread</b>
Procrit (epoetin alfa)	\$950.00 (4000 u/ml 25x1 ml vials)	\$1200	\$250	20.8%
Ultram (tramadol hcl)	\$53.97 (1x100 50 mg)	\$62.34	\$8.37	13.4%
Duragesic fentanyl transdermal)	\$44.94 (25M 25mcg/hr 1x5)	\$53.94	\$9	16.7%
Floxin (ofloxacin)	\$276.89 (1x100 btls 200 mg/case)	\$332.28	\$55.39	16.7%
Propulsid (cisapride)	\$56.62 (10mgx100)	\$67.96	\$11.34	16.7%
Risperdal (risperidone)	\$335.59 (3 mg 1x100)	\$402.72	\$67.13	16.7%
Topamax tiramate)	\$123.00 (100 mg 1x60)	\$147.60	\$24.6	16.7%

## 2. J&J Concealed Its AWP Manipulation

456. J&J deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread. J&J routinely required that its customers keep secret the prices they were being charged for J&J drugs. (J&J001022; J&J000110; J&J001430; J&J001483).

## O. Novartis

457. Novartis engages in an organization-wide and deliberate scheme to inflate AWP's. Novartis has stated fraudulent AWP's for many of its drugs. The specific drugs of Novartis for which relief is sought in this case are set forth in Appendix A.

<b>Manufacturer</b>	<b>Brand Name (if applicable)</b>	<b>Generic Name</b>	<b>Therapeutic Category/Usage</b>
NOVARTIS	Clozaril	clozapine	Antipsychotic (Psychotherapeutic Agent) Used to treat schizophrenia
	Combipatch	estradiol & norethindrone acetate	Hormone Used to treat symptoms of menopause
	Comtan	entacapone	Antidyskinetic Agent Used in combination with levodopa/carbidopa to treat Parkinson's
	Estraderm	estradiol	Antineoplastic; Hormone Used to relieve signs of menopause
	Exelon	rivastigmine tartrate	Cholinesterase Inhibitor (Central Nervous System Agent) Used to treat the symptoms of mild to moderate Alzheimer's disease



Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Femara	letrozole	Antineoplastic Used to treat certain types of breast cancer in women
	Lamisil	terbinafine hcl	Antifungal Agent Used to treat fungus infections of the scalp, body, groin, feet, fingernails, and toenails
	Lamprene	clofazimine	Antibacterial Agent Used to treat leprosy
	Lescol	fluvastatin sodium	HMG-CoA Reductase Inhibitor (Cardiovascular Agent) Used to lower levels of cholesterol and other fats in the blood
	Lotensin	benazepril hcl	ACE Inhibitor (Cardiovascular Agent) Used to treat hypertension
	Lotensin HCT	benazepril & hctz	ACE Inhibitor (Cardiovascular Agent) Used to treat hypertension
	Lotrel	amlodipine besylate- benazepril hcl	ACE Inhibitor (Cardiovascular Agent) Used to treat hypertension
	Miacalcin	calcitonin (salmon)	Calcitonin (Hormone) Used to treat Paget's disease of bone. Also used to prevent continuing bone loss in women with postmenopausal osteoporosis and to treat hypercalcemia
	Parlodel	bromocriptine mesylate	Antidyskinetic Agent; Antihyperprolactinemic; Growth Hormone Suppressant Used to treat certain menstrual problems or to stop milk production. Also used to treat infertility and Parkinson's disease
	Ritalin	methylphenidate hcl	Central Nervous System Stimulant Used to treat attention-deficit hyperactivity disorder (ADHD) and narcolepsy
	Starlix	nateglinide	Antidiabetic Agent Used to treat a type of diabetes mellitus (sugar diabetes) called type 2 diabetes
	Tegretol	carbamazepine	Anticonvulsant; Antipsychotic (Psychotherapeutic Agent) Used to control some types of seizures in the treatment of epilepsy
	Trileptal	oxcarbazepine	Central Nervous System Agent; Anticonvulsant Used in the treatment of partial seizures
	Vivelle	estradiol	Antineoplastic; Hormone Used to relieve signs of menopause

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Vivelle-DOT	estradiol	Antineoplastic; Hormone Used to relieve signs of menopause

## 1. Novartis Has Been the Target of Government Investigations

458. In connection with its scheme to inflate AWP, Novartis has been investigated by the Office of Inspector General of the Department of Health and Human Services. The Office of the Inspector General published a report for the Department of Health and Human Services in 2000 documenting Novartis' inflated AWP for Aredia, its brand of pamidronate disodium.

## 2. Inflated Novartis AWP From Novartis Price Lists

459. As set forth above, Novartis' scheme to inflate its reported AWP and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

## P. Pfizer

460. Pfizer engages in an organization-wide and deliberate scheme to inflate AWP and has stated fraudulent AWP for many of its drugs. The specific drugs of Pfizer for which relief is sought in this case are set forth in Appendix A, and are identified below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
PFIZER	Accupril	quinapril hcl	ACE Inhibitor (Cardiovascular Agent) Used in the treatment of hypertension
	Cardura	doxazosin mesylate	Autonomic Nervous System Agent Used to treat hypertension and benign prostatic hypertrophy
	Eurostep FE	norethindrone-ethinyl estradiol-fe	Oral Contraceptive Also used in the treatment of acne
	Femhrt 1/5	ethinyl estradiol- norethindrone acetate	Estrogen Combination (Hormone) Used in the treatment of menopause and prevention of postmenopausal osteoporosis
	Lipitor	atorvastatin calcium	Antilipemic Agent (Cardiovascular Agent) Used to lower cholesterol
	Nardil	phenelzine sulfate	Antidepressant (Psychotherapeutic Agent) Used in the treatment of depression

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Neurontin	gabapentin	Anticonvulsant Used in the treatment of epilepsy
	Zithromax	azithromycin	Macrolide Antibiotic Agent (Anti-Infective Agent) General antibiotic
	Zoloft	sertraline hcl	Serotonin Reuptake Inhibitor (Psychotherapeutic Agent: Antidepressant) Used in the treatment of depression
	Zyrtec	cetirizine hcl	Antihistamine Used in the treatment of allergic rhinitis

461. Pfizer manufactures and distributes some of the nation's most popular and highest selling brand name drugs.

462. Historically, Pfizer almost never changes the "spread" between the posted AWP and posted WAC for a Pfizer brand name product. Once initially launched, a Pfizer brand name product continues to bear the same difference between the posted AWP and the posted WAC (e.g., 16 2/3%, or 20%, or sometimes 25%).

463. In January 2002, Pfizer announced a prescription drug discount card that would be available to elderly and poor consumers along eligibility criteria similar to that of other discount cards.

464. At the same time, January 2002, Pfizer secretly increased the AWP/WAC spread to 25% for *all* of its brand name drugs. If a drug theretofore had a posted AWP/WAC spread of 20%, it was increased to 25% (something which Pfizer, and indeed all other drug companies, almost never do). If a Pfizer brand name drug already had had a 25% AWP/WAC spread, it remained so.

465. By doing so, Pfizer knew that the purpose and effect of these new listings would be to increase reimbursement payments by end payors by amounts that would be greater than actual transaction costs for other participants in the distribution chain (*i.e.*, wholesalers, distributors, pharmacies and PBMs). Also in doing so, Pfizer knew that the posted AWP's for

many of their brand name drugs would become more misrepresentative of actual average wholesale prices given that the increased AWP/WAC spread bore no relation to actual transaction cost changes occurring in the marketplace.

466. Pfizer has been investigated by the Office of the Inspector General of the Department of Human Health Services and has entered into a \$49 million settlement arising from illegal practices with respect to Lipitor. OIG-HSS found that Pfizer has been providing unrestricted educational grants and rebates that were in fact discounts off the purchase price of Lipitor. Pfizer concealed these discounts from states who were entitled to receive the "best price" for Lipitor.

467. The provision of educational grants and rebates on Lipitor also had the effect of inflating the reported AWP.

468. On information and belief, based in part due to the substantial nature of the spreads between AWP and WAC identified in Appendix A, Pfizer has inflated its AWP on other drugs at issue.

**Q. The Pharmacia Group (Pharmacia and P&U)**

469. The Pharmacia Group engages in an organization-wide and deliberate scheme to inflate AWP's. The Pharmacia Group has stated fraudulent AWP's for all or almost all of its drugs, including those set forth below. The specific drugs of The Pharmacia Group for which relief is sought in this case are set forth in Appendix A, and are set forth below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
PHARMACIA GROUP (Pharmacia and P&U)	Adriamycin	doxorubicin hydrochloride	Antineoplastic Used in the treatment of various forms of cancer
	Adrucil	fluorouracil	Antimetabolite; Antineoplastic Used in the treatment of various forms of cancer
	Amphocin	amphotericin b	Antifungal (Anti-Infective Agent) Used in the treatment of serious fungal infections

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Celebrex	celecoxib	Analgesic; Antirheumatic Agent Used to relieve some symptoms caused by arthritis
	Cleocin-T	clindamycin phosphate (topical)	Antibacterial Agent (Anti-Infective Agent) Used to treat bacterial infections
	Cytosar-U	cytarabine	Antineoplastic Used in the treatment of cancer of the blood
	Depo- Testosterone	testosterone cypionate	Androgen (Hormone) Used to replace hormones or stimulate growth
	Neosar	cyclophosphamide	Alkylating Agent (Antineoplastic) Used in the treatment of various forms of cancer as well as some kidney disease
	Solu-Cortef	hydrocortisone sodium succinate	Anti-Inflammatory Agent; Skin and Mucous Membrane Agent Used to provide relief for inflamed areas of the body. Also used as replacement therapy in adrenocortical insufficiency
	Solu-Medrol	methylprednisolone sodium succinate	Anti-Inflammatory Agent Used to provide relief for inflamed areas of the body. Also used as replacement therapy in adrenocortical insufficiency
	Toposar	etoposide	Antineoplastic Used in the treatment of testicular and lung cancer
	Vincasar	vincristine sulfate	Antineoplastic Used in the treatment of various forms of leukemia and cancer
		bleomycin sulfate	Antineoplastic; Antibiotic Agent (Anti-Infective Agent) Used in the treatment of various forms of cancer

### 1. The Pharmacia Group Has Been the Target of Government Investigations

470. In connection with its scheme to inflate AWP's, The Pharmacia Group has been investigated by the Department of Justice, the Texas Attorney General, the California Attorney General, the Massachusetts Attorney General, the Attorney General of the State of Connecticut, the Attorney General of the State of New York, and the Department of Health and Human Services Office of Inspector General.

## **2. Pharmacia's Definition and Understanding of AWP**

471. Pharmacia understands that third party reimbursement is based on its published AWP. According to a "Strategic Presentation on Average Wholesale Price (AWP)" prepared by P&U, the "Definition of AWP" is:

An artificial pricing index that is used as a common basis for third-party reimbursement to pharmacists and physicians.

-The difference between the published AWP (less a percentage) and the direct price is the profit margin that drives these classes of trade.

(PH 025785) (Highly Confidential). During this same presentation, Pharmacia provided an "AWP History":

- ◆ Historically, Wholesalers viewed AWP as an actual average selling price to their customers.
- ◆ Competition of 1980's led to AWP representing a "Suggested List Price"
- ◆ P&U AWP = 125% of Direct Price (DP)
- ◆ Exceptions being VANTIN, CVC, GENOTROPIN, and RESCRIPTOR = 120% of DP

(PH025791) (Highly Confidential). Further, the presentation recognized that "'95 Medicare (Part B) outpatient drug bill (I.V./inhalants/oncolitics/nutritionals) of \$1.8 billion based primarily on AWP." (PH025793) (Highly Confidential).

## **3. The Pharmacia Group Controls the Published AWP for Its Products**

472. The Pharmacia Group has controlled and set the AWP for its pharmaceutical products through direct communications with industry compendia during the Class Period. In its presentation entitled "Strategic Presentation on Average Wholesale Price (AWP)," P&U included a flow chart that shows P&U communicates its AWP to First Data Bank, Medi-Span and *Red Book*. This same flow chart then shows that third party payors rely on these industry compendia for prices. (PH025792) (Highly Confidential).

**4. The Pharmacia Group's AWP Manipulation Benefited Providers at the Expense of the Class**

473. The Pharmacia Group has engaged in an ongoing deliberate scheme to inflate AWP's. According to one member of the Congressional Ways and Means Committee:

The evidence . . . indicates that [Pharmacia & Upjohn] have knowingly and deliberately inflated their representations of the average wholesale price ("AWP"), wholesale acquisition cost ("WAC") and direct price ("DP") which are utilized by the Medicare and Medicaid programs in establishing drug reimbursements to providers.

\* \* \*

[T]hese practices must stop and . . . these companies must return the money to the public that is owed because of their abusive practices.

See Extension of Remarks of U.S. Representative Pete Stark in the House of Representatives, October 3, 2000 (P007545-P007547).

474. In a letter dated October 3, 2000 to Pharmacia (with accompanying exhibits), Representative Stark addressed the Pharmacia Group's illegal practices:

The manipulated disparities between your company's reported AWP's and DP's are staggering. For example, in 1997, Pharmacia & Upjohn reported an AWP of \$946.94 for 200 mg. of Adriamycin PFS while offering to sell it to American Oncology Resources (AOR) for \$168.00 and to Comprehensive Cancer Center for \$152.00 (Composite Exhibit "1"). Your company then aggressively marketed its cancer drugs to health care providers by touting financial inducements and other types of incentives. Pharmacia & Upjohn created and marketed the financial inducements for the express purpose of influencing the professional judgment of doctors and other health care providers in order to increase the company's market share.

\* \* \*

Pharmacia & Upjohn's own internal documents . . . reveal that the company abused its position as a drug innovator in an initial *Phase III* FDA clinical trial for a cancer drug used to treat lymphoma (Composite Exhibit "2") (emphasis in original).

"... Clinical Research Trials



Initial Phase III Protocol trial for "Oral Idamycin" in lymphomas. This trial will offer AOR \$1.1M [million] in additional revenues. Two hundred twenty-five (225) patients at \$5,000 per patient . . . (emphasis added by Rep. Stark)

The above . . . items are contingent on the signing of the AOR Disease Management Partner Program. AOR's exclusive compliance to the purchase of the products listed in the contract product attachment is also necessary for the above items to be in effect."

The linking of doctor participation in FDA clinical drug trials to their purchase and administration of profit-generating oncology drugs is entirely inconsistent with the objective scientific testing that is essential to the integrity of the trial.

\* \* \*

It is clear that Pharmacia & Upjohn targeted health care providers, who might be potential purchasers, by creating and then touting the windfall profits arising from the price manipulation. For example, Pharmacia & Upjohn routinely reported inflated average wholesale prices for its cancer drug Bleomycin, 15u, as well as direct prices. The actual prices paid by industry insiders was in many years less than half of what Pharmacia & Upjohn represented. Pharmacia & Upjohn reported that the average wholesale price for Bleomycin, 15u, rose from \$292.43 to \$309.98, while the price charged to industry insiders fell by \$43.15 (Composite Exhibit "4").

\* \* \*

Pharmacia & Upjohn reported price increases in October 1997 with full knowledge that the true prices of the drugs were falling. For example, Composite Exhibit "7" reveals that Pharmacia & Upjohn voluntarily lowered its price of Adriamycin PFS 200 mg to \$152.00 while reporting an AWP of \$946.94:

"Dear Willie,

A (VPR) Voluntary Price Reduction will become effective May 9, 1997. The wholesalers have been notified, however it may take two weeks to complete the transition . . ."

Additionally, internal Pharmacia & Upjohn documents secured through the Congressional investigations show that Pharmacia & Upjohn also utilized a large array of other inducements to stimulate product sales. These inducements, including "educational grants" and free goods, were designed to result in a lower net cost to the purchaser while concealing the actual price beneath a high invoice

price. Through these means, drug purchasers were provided substantial discounts that induced their patronage while maintaining the fiction of a higher invoice price – the price that corresponded to reported AWP and inflated reimbursements from the government. Composite Exhibit “8” highlights these inducements:

AOR/PHARMACIA & UPJOHN PARTNERSHIP PROPOSAL: Medical Education Grants. A \$55,000 grant has been committed for 1997 for the AOR Partnership for excellence package including Education/Disease Management, Research Task Force, AOR Annual Yearbook. A \$40,000 grant to sponsor the AOR monthly teleconference. This sponsorship was committed and complete in February 1997 . . .

PHARMACIA & UPJOHN, INC. INTEROFFICE MEMO: If needed, you have a “free goods” program to support your efforts against other forms of generic doxorubicin . . .

Use your “free goods” wisely to compete against other generic forms of Adriamycin, not to shift the customer to direct shipments. The higher we can keep the price of Adriamycin, the easier it is for you to meet your sales goals for Adriamycin (emphasis added by Rep. Stark).

(P007613-P007632).

475. Pharmacia’s marketing pitches, as quoted by U.S. Rep. Pete Stark in a September 28, 2000 letter to Alan F. Holmer, President of the Pharmaceutical Research and Manufacturers of America, promoted a physician’s ability to profit at the expense of Medicare and its beneficiaries:

PHARMACIA: Some of the drugs on the multi-source list offer you savings of over 75% below list price of the drug. For a drug like Adriamycin, the reduced pricing offers AOR a reimbursement of over \$8,000,000 profit when reimbursed at AWP. The spread from acquisition cost to reimbursement on the multi-source products offered on the contract give AOR a wide margin for profit.

(P007548-P007588).

476. In 1997, Pharmacia sent to a clinic a proposal listing the AWP and the contract price at which several drugs would be sold to the provider. The differences are staggering and just a few are noted below:

Drug	AWP	Suggested New Contract Price
Adriamycin (10 mg)	46.00	7.50
Adriamycin (50 mg)	230.00	37.50
Neosar (2 g)	86.00	18.00
Toposar (1 g)	1,330.75	120.00
Vincasar (2 mg)	741.50	7.50

(P007615).

##### 5. Specific Pharmacia AWP's Documented by the DOJ

477. In a report published by the DHHS, the DOJ documented at least 43 instances where the published AWP's for various dosages of drugs manufactured by The Pharmacia Group were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by The Pharmacia Group in the 2001 *Red Book*.

Drug	The Pharmacia Group's 2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Spread
Amphotercin B	\$36.26	\$16.00	\$20.26	127%
Bleomycin Sulfate	\$309.98 <sup>8</sup>	\$158.67	\$151.31	96%
Clindamycin Phosphate	\$93.60	\$61.20	\$32.40	53%
Cyclophosphamide	\$6.29	\$3.92	\$2.37	60%
Cytarabine	\$8.98	\$4.06	\$4.92	122%
Doxorubicin HCL	\$1104.13	\$150.86	\$953.27	632%
Etoposide	\$157.65	\$9.47	\$148.18	1,565%
Fluorouracil	\$3.20	\$1.47	\$1.73	118%
Hydrocortisone Sodium Succinate	\$2.00	\$1.55	\$.45	29%
Metholprednisolone	\$2.05	\$1.45	\$.60	41%

<sup>8</sup> Calculation based on the AWP listed in the 2000 *Red Book*.

Sodium Succinate				
Testosterone Cypionate	\$17.01	\$11.79	\$5.22	44%
Vincristine Sulfate	\$43.23	\$5.10	\$38.13	748%

478. In OIG report OEI-03-00-00310, the government noted that 20 mg of irinotecan, which according to the *Red Book* is manufactured only by The Pharmacia Group, had a Medicare Median of \$117.81 and a Catalog Median of \$98.63, resulting in a spread of 19.45%. (P006398-P006424).

479. The GAO issued a report entitled "Payments for Covered Outpatient Drugs Exceed Providers' Cost" (GAO-01-1118) wherein it found that irinotecan had an Average AWP of \$141.32, the Average Widely Available Discount from AWP to physicians for irinotecan was 22.9%, and the drug constituted 2.0% of the total amount of Medicare spending in 1999. (P005546-P005578).

480. As of April 2000, another Pharmacia Group drug, Toposar® (etoposide), had an AWP of \$28.38. The DOJ found that retailers were buying it for \$1.70. (P006299-006316).

481. Similarly, by letter dated September 25, 2000 to the HCFA Administrator, the Chairman of the Commerce Committee revealed that:

[I]n 1998, Pharmacia-Upjohn's Bleomycin had an AWP of \$309.98, but health care providers could purchase it for \$154.85. In 1997, Pharmacia-Upjohn's Vincasar could be purchased for \$7.50, while the AWP was a staggering \$741.50.

See letter dated May 25, 2000 from U.S. Rep. Thomas J. Bliley to Nancy-Ann Min DeParle, HCFA Administrator. (P007015-P007490).

482. Exhibit 1 to U.S. Rep. Pete Stark's September 28, 2000 letter to Alan F. Holmer, President of the Pharmaceutical Research and Manufacturers of America, reveals that while the AWP for 1 mg of Vincasar® (vincristine sulfate) was \$370.75 in 1997, one physician group's (American Oncology Resources) price in 1997 was only \$4.15. (P007515). Similarly, while the AWP for 2 mg of Vincasar® was \$741.50, AOR's actual pre-April 1997 price was \$7.75 (in fact,

The Pharmacia Group had offered to reduce it to \$7.50). *Id.* As of April 2000, Adriamycin had a reported AWP of \$241.36, while the real wholesale price was \$33.43.

#### 6. Inflated Pharmacia AWP's From Pharmacia's Price Lists

483. According to Pharmacia's own documents, the published AWP's for its drugs were higher than the actual prices provided to wholesalers. In response to government subpoenas, the Pharmacia Group produced numerous price lists setting forth spreads between AWP's and prices apparently offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Pharmacia has consistently offered hundreds of its drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spread offered to each specific customer here is not practical. However, set forth below in Table 1 are a number of those drugs with spreads between the AWP's and direct prices. Table 1 is an analysis of certain dosages of P&U drugs from a document entitled "Oncology Express CONTRACT PRICING" (PH011977) (Highly Confidential).

**Table 1**

PRODUCT	LIST	AWP	CONTRACT PRICE	DIFFERENCE (between AWP and contract price)	PERCENTAGE SPREAD
Adriamycin	883.80	1104.13	119.00	985.13	828%
Adrucil	12.83	16.04	4.56	11.48	252%
Amphocin	29.01	36.26	13.00	23.26	179%
Neosar	80.22	100.28	16.15	84.13	521%
Toposar	614.81	768.51	33.84	734.67	2,171%

#### 7. The Pharmacia Group Provided Free Goods and Other Incentives

484. In addition to marketing the spread, The Pharmacia Group has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. By utilizing "off-invoice" inducements, The Pharmacia Group provided

purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

485. The government investigators also uncovered an October 3, 1996 internal memorandum wherein Pharmacia told three oncology sales representatives:

Our competitive intelligence tells us that our pricing on Adriamycin, although higher than generics, is in the "ball park" for you to attain the customers Adriamycin business. If needed, you have a "free goods" program to support your efforts against other forms of generic doxorubicin.

....

You should not have to use "free goods" to steer customer [sic] away from NSS or OTN. OTN and NSS Adriamycin pricing is competitive. Use your "free goods" wisely to compete against other generic forms of Adriamycin, not to shift the customer to direct shipments. The higher we can keep the price of Adriamycin, the easier it is for you to meet your sales goals for Adriamycin.

(PH 024315).

486. As set forth above, The Pharmacia Group's scheme to inflate its reported AWP's and market the resulting spread to increase the market share of its drugs and its use of other "off invoice" rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

#### **R. The Schering-Plough Group (Schering-Plough and Warrick)**

487. The Schering Plough Group engages in an organization-wide and deliberate scheme to inflate AWP's. The Schering Plough Group has stated fraudulent AWP's for all or almost all of its drugs, including those set forth below. The specific drugs of The Schering Plough Group for which relief is sought in this case are set forth in Appendix A, and are set forth below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
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Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
SCHERING- PLOUGH GROUP	Clarinox	desloratadine	Antihistamine Used to relieve the symptoms of hay fever and hives of the skin
(Schering-Plough and Warrick)	Claritin	loratadine	Antihistamine Used to relieve or prevent the symptoms of asthma
	Claritin-D	loratadine & pseudoephedrine	Antihistamine Used to treat the nasal congestion, sneezing, and runny nose caused by colds and hay fever
	Diprolene	aug betamethasone dipropionate	Antipruritic (Skin & Mucous Membrane Agent) Used to help relieve redness, swelling, itching, and discomfort of many skin problems
	Diprosone	betamethasone dipropionate	Antipruritic (Skin & Mucous Membrane Agent) Used to help relieve redness, swelling, itching, and discomfort of many skin problems
	Elocon	mometasone furoate	Antipruritic (Skin & Mucous Membrane Agent) Used to help relieve redness, swelling, itching, and discomfort of many skin problems
	Eulexin	flutamide	Antineoplastic Used to treat cancer of the prostate gland
	Integrilin	eptifibatide	Cardiovascular Agent Used in the treatment of patients with acute coronary syndrome
	Intron-A	interferon alfa-2b	Immunomodulator Used in the treatment of hairy cell leukemia and chronic hepatitis B or C.
	Lotrisone	clotrimazole w/ betamethasone	Antifungal Agent (Anti-Infective Agent) Used to treat fungus infections
	Nasonex	mometasone furoate (nasal)	Anti-Inflammatory Agent (Nasal Preparation) Relieve the stuffy nose, irritation, and discomfort of hay fever and other allergies
	Peg-Intron	peginterferon alfa-2b	Biological Response Modifier Used to treat chronic hepatitis C
	Proventil	albuterol sulfate	Bronchodilator (Respiratory Agent) Used to treat the symptoms of asthma, chronic bronchitis, emphysema, and other lung diseases
	Rebetol	ribavirin	Biological Response Modifier Used to treat hepatitis C
	Sebizon	sulfacetamide sodium	Anti-Infective Agent Used in the treatment of conjunctivitis and other ocular infections
	Temodar	temozolomide	Antineoplastic Used to treat a specific type of cancer of the brain in adults whose tumors have returned



Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	Trinalin Rep	azatadine & pseudoephedrine	Antihistamine Used to treat the nasal congestion, sneezing, and runny nose caused by colds and hay fever.
	Vanceril	beclomethosone (nasal)	Anti-Inflammatory Agent; Antiasthmatic Used to help prevent the symptoms of asthma
		albuterol	Bronchodilator (Respiratory Agent) Used for relief of bronchospasm in asthma sufferers
		clotrimazole	Antifungal Agent (Anti-Infective Agent) Used to treat yeast (fungus) infections of the vagina
		griseofulvin ultramicrocrystalline	Antifungal Agent (Anti-Infective Agent) Used to treat fungus infections of the skin, hair, fingernails, and toenails
		oxaprozin	Central Nervous System Agent; Antipyretic (Analgesic) Used in the treatment of osteoarthritis and rheumatoid arthritis
		perphenazine	Antiemetic (Gastrointestinal Agent); Antipsychotic Agent (Psychotherapeutic Agent) Used to treat serious mental and emotional disorders. Also used to relieve moderate to severe pain in some hospitalized patients
		potassium chloride	Electrolytic Agent Used to prevent and treat potassium deficit secondary to diuretic or corticosteroid therapy
		sodium chloride	Flush; Abortifacient Used to remove medicine and blockage from intravenous (IV) catheter. Also used to induce abortion
		sulcrafate	Gastrointestinal agent Used for short term treatment of duodenal ulcer
		theophylline er	Bronchodilator (Respiratory Agent) Used to treat and/or prevent the symptoms of bronchial asthma, chronic bronchitis, and emphysema

# **1. The Schering Plough Group Has Been the Target of Government Investigations**

488. In connection with its scheme to inflate AWP's, The Schering Plough Group has been investigated by the Department of Justice, Texas Attorney General, West Virginia Attorney General, California Attorney General, California Bureau of Medi-Cal Fraud and Elder Abuse,

and the Department of Health and Human Services Office of Inspector General, and the U.S. Attorney for the District of Massachusetts.

489. On May 30, 2003, Schering Plough announced that the U.S. Attorney for the District of Massachusetts had advised that its subsidiary, Schering Corporation, is the subject of a federal grand jury investigation. Schering Plough is the target of a criminal investigation involving: (i) providing remuneration, such as drug samples, to providers to induce the purchase of Schering products for which payment was made through federal health care programs; (ii) selling misbranded or unapproved drugs; (iii) submitting false wholesale pricing information for its pharmaceutical products to the government; and (iv) destroying evidence and obstructing justice relating to the government's investigation. *See* Schering Plough Press Release dated May 30, 2003, located at <http://www.sch-plough.com/news/2003/business/20030530.html>; "Schering Plough expects indictment," *The Philadelphia Inquirer*, at C3 (May 31, 2003). Moreover, according to Schering Plough's Form 10-K for the year 2000, this investigation has focused on "whether the AWP set by pharmaceutical companies for certain drugs improperly exceeds the average prices paid by dispensers . . . and other pricing and/or marketing practices."

490. A Medicaid investigation by the Texas Attorney General revealed that The Schering-Plough Group defrauded the State of Texas \$14.5 million. Investigators determined that The Schering-Plough Group provided the greatest "spread" amongst the drug companies selling albuterol in Texas, and thereby obtained the largest market share for albuterol. The Schering-Plough Group sold a box of albuterol to pharmacies for \$13.50, while it charged the Texas Medicaid program \$40.30, a 200% increase. *See Cornyn Sues Three Drug Companies for Medicaid Fraud*, Press Release by the Office of the Attorney General, State of Texas, Sept. 7, 2000. ([www.oag.state.tx.us.gov](http://www.oag.state.tx.us.gov))

491. On October 11, 2001, the West Virginia Attorney General filed suit against Warrick, alleging that Warrick defrauded state agencies and citizens by deliberately overstating the AWP for certain drugs, including albuterol, from approximately 1995 until December 2000.

## **2. The Schering Plough Group Controls the Published AWP for Its Products**

492. The Schering Plough Group has controlled and set the AWP for its pharmaceutical products through direct communications with industry compendia during the Class Period. For example, on February 23, 1995, Warrick sent a letter to First Data Bank, stating:

Effective Friday, February 24, 1995, at 5:00 p.m., the price of Warrick Albuterol Solution 0.5% 20ml will increase as follows:

	<u>NDC</u>	<u>AWP</u>
	<u>59930-</u>	
Albuterol Solution 0.5% 20 ml	1515-04	\$13.95

(WAR0024086) (Highly Confidential).

## **3. The Schering Plough Group's AWP Manipulation Benefited Providers at the Expense of the Class**

493. A Schering Laboratories memorandum dated May 20, 1993 demonstrates Defendant's recognition that intermediaries choose drugs based on favorable AWP spreads. At the generic launch of albuterol, Schering stated:

Proventil will stay listed at AWP; therefore, Proventil is a favored product for third party reimbursement that provides for the AWP minus 10% reimbursement rate to chains. Thus, they can buy off the Proventil deal and bill at AWP.

(WAR005419-20) (Highly Confidential).

494. According to Warrick's own documents, Warrick consistently maintained a spread between the AWP and the direct prices it offered for its albuterol products. For example, a "Price Change" alert dated June 7, 1999 sent to Warrick customers provides:

<u>Product</u>	<u>Pkg.</u>	<u>NDC</u>	<u>AWP</u>	<u>Direct</u>
	<u>Size</u>	<u>59930</u>		<u>Price</u>

Albuterol Inhalation Aerosol	17 g	1560-1	\$21.41	\$3.40
Albuterol Aerosol Refill	17 g	1560-2	\$19.79	\$3.40

(WAR0000532) (Highly Confidential). Thus, Warrick touted a 529% spread on its albuterol inhalation aerosol and a 482% spread on the refill.

495. In a report to Congress, the GAO reported that albuterol sulfate was one of a small number of products that accounted for the majority of Medicare spending and volume. Albuterol sulfate accounted for 6.3% of total Medicare spending, ranking fifth out of more than 400 covered drugs. Albuterol sulfate ranked first for volume of units covered, accounting for 65.8% of total units reimbursed. *See* GAO Report to Congressional Committees, "Payments for Covered Outpatient Drugs Exceed Providers' Cost," Tables 1 and 2, pp. 7-8 (GAO-01-0118 (P005546-005578)). The Schering Plough Group is one of three companies noted by the DOJ as manufacturing albuterol. *See* DHHS report, AB-00-86 (P006299-006316).

496. According to The Schering Plough Group's own documents, the published AWP's for most of its drugs were higher than the actual prices provided to wholesalers.

497. In response to government subpoenas, The Schering Plough Group produced numerous price lists setting forth spreads between AWP's and prices apparently offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Warrick has consistently offered hundreds of its drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spread offered to each specific customer here is not practical. However, set forth below in Tables 1, 2 and 3 are a number of those drugs with spreads between the AWP's and direct prices. Table 1 is an analysis of certain dosages of Warrick drugs from a document entitled, "Amerisource" (WAR0022160) (Highly Confidential).

**TABLE 1**

LABEL (MFG)	GENERIC NAME	AWP	INVOICE COST	DIFFERENCE	PERCENTAGE SPREAD
Warrick	Albuterol Inhaler	21.41	5.75	15.66	272%
	Aug Beta Dip Oint	43.20	26.90	16.30	61%

LABEL (MFG)	GENERIC NAME	AWP	INVOICE COST	DIFFERENCE	PERCENTAGE SPREAD
	0.05%				
	Griseofulvin	82.47	37.22	45.25	122%
	Theophylline	11.70	2.83	8.87	313%

Table 2 is an analysis of certain dosages of Warrick drugs from a document entitled, "1997 Care Group Bid Proposal." (WAR0022122) (Highly Confidential).

**TABLE 2**

PRODUCT	AWP	INVOICE PRICE	NET PRICE (AFTER REBATE)	DIFFERENCE BETWEEN AWP AND INVOICE PRICE	PERCENTAGE SPREAD
Clotrimazole	22.25	7.77	6.99	14.48	186%
Perphenazine	78.00	19.53	17.58	58.47	299%

Table 3 is an analysis of certain dosages of Warrick drugs from a document entitled, "Managed Care Pricing," dated July 1, 2002. (WAR0054226) (Highly Confidential).

**TABLE 3**

Product	Minimum PBM/Mail Order/ Staff Price Guide	Target PBM/Mail Order/ Staff Price Guide	Minimum GPO Price Guide	Target GPO Price Guide	AWP	Difference	% Spread
ISMN	4.48	4.93	5.15	5.38	117.40	112.02	2,082%
Oxaprozin	11.42	12.56	13.13	13.70	117.40	103.70	757%
Potassium Chloride	9.67	10.64	11.12	11.60	65.00	53.40	460%
Sodium Chloride	6.12	6.73	7.04	7.34	24.30	16.96	231%
Sulcrafate Tablets	45.15	49.67	51.92	54.18	353.71	299.53	553%

#### **4. The DOJ Specifically Documented AWP Inflation for Albuterol Sulfate**

498. In a report published by the DHHS (AB-00-86 (P006299-006316)), the DOJ documented at least one instance where the published AWP for various dosages of albuterol sulfate manufactured by The Schering Plough Group were substantially higher than the actual prices listed by wholesalers. The following figures compare the DOJ's determination of an accurate AWP for one particular dosage, based upon wholesalers' price lists, with the AWP

reported by The Schering Plough Group in the 2001 *Red Book*: The Schering-Plough Group reported to *Red Book* an AWP of \$30.25 for albuterol sulfate, yet the DOJ determined the actual AWP to be \$9.16, or \$21.09 less.

499. As stated in a May 4, 2000, letter from U.S. Rep. Tom Bliley, Chairman of the Congressional Committee on Commerce, to Raman Kapur, President of Warrick:

I am writing to you because one of the drugs reflecting a significant variation between the AWP-based prices paid by Medicare and the prices generally charged to private sector purchasers is albuterol sulfate, a drug manufactured by Warrick Pharmaceuticals.

(P006938-006941).

500. In his May 4, 2000, letter, Bliley outlined The Schering Plough Group's scheme with respect to the prescription drug albuterol sulfate. The government's investigation uncovered a significant spread between the amount Medicare reimbursed for albuterol sulfate and the amount the Schering-Plough Group actually charged. U.S. Rep. Bliley stated:

The OIG [Office of the Inspector General] has determined that the Medicare-allowed amount for albuterol sulfate, a pharmaceutical product sold by your company, in the Fiscal Year 1996 was \$.42. The OIG further estimated that the actual wholesale price of this drug was \$.15 and the highest available wholesale price that the OIG was able to identify was \$.21.

*Id.*

##### **5. The Schering Plough Group Provided Free Goods and Other Incentives**

501. In addition to marketing the spread, The Schering Plough Group has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. By utilizing "off-invoice" inducements, The Schering Plough Group provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

502. As set forth above, The Schering Plough Group's scheme to inflate its reported AWP's and market the resulting spread to increase the market share of its drugs and its use of other "off invoice" rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

**S. The Sicor Group (Sicor, Gensia and Gensia Sicor)**

503. The Sicor Group engages in an organization-wide and deliberate scheme to inflate AWP's. The Sicor Group has stated fraudulent AWP's for all or almost all of its drugs, including those set forth below. The specific drugs of The Sicor Group for which relief is sought in this case are set forth in Appendix A, and are identified below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
SICOR GROUP (Sicor, Gensia and Gensia-Sicor)		acyclovir sodium	Anti-Infective Agent Used in the treatment of herpes infections
		amikacin sulfate	Antibiotic Agent (Anti-Infective Agent) Used to treat respiratory tract, urinary tract, bone, skin and soft tissue infections
		amphotercin b	Antifungal Agent (Anti-Infective Agent) Used to help the body overcome serious fungus infections
		doxorubicin hydrochloride	Antineoplastic Used in the treatment of ovarian cancer and AIDS-related Kaposi's sarcoma
		etoposide	Mitotic Inhibitor (Antineoplastic) Used in the treatment of testicular neoplasm and small cell cancer of the lung
		leucovorin calcium	Antianemic Agent (Blood Modifier) Used in the treatment of anemia
		pentamidine isethionate	Anti-Infective Agent Used in the treatment of pneumonia
		tobramycin sulfate	Antibiotic Agent (Anti-Infective Agent) Used to treat severe infection



## 1. The Sicor Group Has Been the Target of Government Investigations

504. In connection with its scheme to inflate AWP, The Sicor Group has been investigated by the Department of Justice, Department of Health and Human Services Office of Inspector General, the Texas Department of Health, and the California Attorney General.

## 2. The Sicor Group Controls the Published AWP for Its Products

505. The Sicor Group has controlled and set the AWP for its pharmaceutical products through direct communications with industry compendia during the Class Period. For example, by letter dated February 21, 1994, Gensia advised MediSpan of the impending launch of its new product called "Etoposide" and stated: "I have also include [sic] some guidelines in this pack for establishing Gensia's AWP for our Etoposide." (SICOR 00955) (Confidential). That same day, Gensia sent a second letter to MediSpan stating, in part:

The following represents the detailed information for this product and the AWP that we would like MediSpan to use:

### ETOPOSIDE INJECTION

<u>NDC #</u>	<u>PRODUCT DESC.</u>	<u>VIALSIZE</u>	<u>LIST PRICE</u>	<u>AWP</u>
0703-5643-01	20MG/ML (100MG)	5ML	\$105.16	\$131.30
0703-5646-01	20MG/ML (500MG)	25ML	\$483.74	\$638.76

(SICOR 00956).

506. Moreover, The Sicor Group has told its sales force to rely on the AWP information contained in the industry compendia when marketing to customers. For example, a memorandum dated April 6, 1994 to "Field Sales force" regarding "Average Wholesale Prices (AWP)" provides in pertinent part:

Attached is a copy of Medi-Span's March 31, 1994 printout of product and AWP information for Gensia Laboratories. Since this information comes directly from Medi-Span's computer file, you will find it to be more accurate than the information that your customers are using from their reference texts. You will note, that the AWP information (listed in pack quantity) is found in the third column from the right. Additionally, the two columns to the immediate left of the AWP column represent: WAC (Wholesalers Acquisition Cost) and DP (Direct Price).

(SICOR 00753) (Highly Confidential).

**3. The Sicor Group's AWP Manipulation Benefited Providers at the Expense of the Class**

507. The Sicor Group has engaged in an ongoing deliberate scheme to inflate AWP's. For example, by letter dated September 25, 2000 to the HCFA administrator, the Chairman of the Commerce Committee revealed that: "[I]n 1998, a health care provider could buy Gensia's Etoposide for \$14.00, while the AWP used to determine Medicare reimbursement was \$141.97." (P007015-P007490).

508. The Sicor Group's marketing strategies further demonstrate its fraudulent practices. In a marketing document prepared by Gensia and obtained by the government in its investigation, Gensia stated:

Concentrate field reps on the top 40 AIDS hospitals using a \$54.00 price in conjunction with a 10% free goods program to mask the final price. Provides the account with an effective price of \$48.60 per vial.

See letter dated September 28, 2000 from U.S. Rep. Pete Stark to Alan F. Holmer, President of the Pharmaceutical Research and Manufacturers of America. (P007512).

509. Certain handwritten notations appear on this same marketing document comparing the AWP with other prices used for the same drug:

FSS \$44.95  
Whls \$71.00  
Distr. \$51.50  
AWP \$109.20

(P007532).

510. Similarly, a document entitled "Comparison of AWP's" based on the 1996 *Red Book* contains the following handwritten notation:

Rob, Joe,

Tim suggested sending this info to the reps. Your thoughts?

B

(SICOR 00756) (Highly Confidential). Following this notation is a chart comparing the AWP for certain drugs published by various manufacturers, including Gensia. One example follows:

Doxorubicin		Abbott/ Adria	Bedford	FUSA	Gensia			
					X			
10		\$48.31	\$47.35	\$44.50	<b>\$49.29</b>	<Polymer		
					X			
50		\$241.56	\$236.74	\$231.00	<b>\$246.46</b>	<Polymer		
					X			
200		\$946.94	\$945.98	NA	<b>\$966.14</b>	<Polymer		

*Id.*

511. Moreover, Gensia disseminated advertisements that actually contained a comparison of the Contract Price with the AWP and set forth the resulting spread (SICOR 00751, 00752) (Highly Confidential), because Gensia knew that marketing the spread was in its best interests. Realizing this, one customer of Gensia, Opti Care, sent a memorandum to all its offices (with a copy to Gensia) stating: "Gensia's products offer a significant spread between AWP and contract price. This spread may be attractive, when a payor's reimbursement is based on AWP and the drug is not MAC'd. (SICOR 00758) (Highly Confidential).

#### 4. Specific Sicor Group AWP's Documented by the DOJ

512. In a report published by the DHHS, the DOJ documented at least 17 instances where the published AWP's for various dosages of drugs manufactured by The Sicor Group were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by The Sicor Group in the 2001 *Red Book*.

Drug	The Sicor Group's 2001 <i>Red Book</i> AWP	DOJ Determined Actual AWP	Difference	Spread
Acyclovir Sodium	\$125.00 <sup>9</sup>	\$100.00	\$25.00	25%
Amikacin Sulfate	\$87.50	\$72.68	\$14.82	20%
Tobramycin Sulfate	\$342.19	\$6.98	\$335.21	4,802%

(P006299-006316).

### 5. Inflated Sicor Group AWP's From the Sicor Group's Price Lists

513. According to The Sicor Group's own documents, the published AWP's for its drugs were higher than the actual prices provided to wholesalers. In response to government subpoenas, The Sicor Group produced numerous price lists setting forth spreads between AWP's and prices apparently offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that The Sicor Group has consistently offered hundreds of its drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spread offered to each specific customer here is not practical. However, set forth below in Tables 1 and 2 are a number of those drugs with spreads between the AWP's and direct prices. Table 1 is an analysis of certain dosages of two Gensia drugs from a Medi-Span printout on which Gensia wanted its sales force to rely (the remaining drugs were redacted by The Sicor Group prior to production). (SICOR 00754-755) (Highly Confidential).

**Table 1**

Product	WAC	DP	AWP	DIFFERENCE (between AWP and DP)	PERCENTAGE SPREAD
Etoposide Inj	483.73	483.73	638.76	155.03	32%
Leucovorin CA Inj	32.50	32.50	40.63	8.13	25%

514. Table 2 is an analysis of certain dosages of four Gensia drugs from multiple Gensia price lists for a particular customer, Pharmaceutical Buyers, Inc., comparing the customer's Contract Price with the AWP and the resulting spread (the remaining drugs were

<sup>9</sup> Calculation based on the AWP listed in the 2000 *Red Book*.

redacted by The Sicor Group prior to production). (SICOR 00555, 573, 614, 633) (Highly Confidential).

**Table 2**

Product	AWP	PBI CONTRACT	SPREAD	PERCENTAGE SPREAD
DOXURUBICIN HYDROCHLORIDE	871.70	293.60	578.10	1,969%
ETOPOSIDE	1207.33	456.00	751.33	1,648%
LEUCOVORIN CALCIUM	39.00	4.58	34.42	752%
PENTAMIDINE ISETHIONATE	468.00	193.75	274.25	1,415%

#### **6. The Sicor Group Provided Free Goods and Other Incentives**

515. In addition to marketing the spread, The Sicor Group has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. By utilizing "off-invoice" inducements, such as free goods, The Sicor Group provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price. (SICOR 00718, 04182, 00689) (Highly Confidential).

516. As set forth above, The Sicor Group's scheme to inflate its reported AWP's and market the resulting spread to increase the market share of its drugs and its use of other "off invoice" rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

#### **T. TAP**

517. TAP engages in an organization-wide and deliberate scheme to inflate AWP's. TAP has stated fraudulent AWP's for Prevacid, as set forth in Appendix A, and identified below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
TAP	Prevacid	lansoprazole	Proton Pump Inhibitor (Gastrointestinal Agent) Used in the short-term treatment of duodenal ulcer, erosive esophagitis and gastroesophageal reflux disease

**1. TAP Has Been the Target of Government Investigations**

518. In connection with its scheme to inflate AWP's, TAP has been investigated by the Department of Justice.

519. On October 13, 2001, the United States Attorney in Boston, Massachusetts announced that TAP had agreed to pay \$875 million to resolve criminal charges and civil liabilities in connection with its fraudulent pricing and marketing practices for the drug named Lupron®. As part of the agreement:

a. TAP agreed to plead guilty to a conspiracy to violate the Prescription Drug Marketing Act, 21 U.S.C. §§ 331(t) and 333(b), and to pay a \$290 million criminal fine, the largest criminal fine ever in a health care fraud prosecution. The plea agreement between the United States and TAP specifically stated that TAP's criminal conduct caused the Government losses of \$145,000,000;

b. TAP agreed to pay the United States Government \$559,483,560 for filing false and fraudulent claims with the Medicare and Medicaid programs as a result of TAP's fraudulent drug pricing schemes and sales and marketing misconduct;

c. TAP agreed to pay the fifty states and the District of Columbia \$25,516,440 for filing false and fraudulent claims with the States, as a result of TAP's drug pricing and marketing misconduct, and for TAP's failure to provide state Medicaid programs TAP's best price for Lupron®, as required by law;

d. TAP agreed to comply with the terms of a sweeping Corporate Integrity Agreement that, among other things, significantly changes the manner in which TAP supervises its marketing and sales staff and ensures that TAP will report to the Medicare and Medicaid programs the true average sale price for drugs reimbursed by those programs;

e. Abbott and Takeda agreed to cooperate fully with the ongoing government investigation of TAP and its former officers and employees in exchange for the United States declining prosecution of Abbott and Takeda for conduct relating to Lupron®; and

f. An Indictment was unsealed in the District of Massachusetts against six current or former TAP employees (including an account executive, three District Managers, a National Accounts Manager and the former Vice President of Sales), and a urologist, alleging that they conspired to (i) bill Medicare for free samples of Lupron® and (ii) market Lupron® using the “spread” and the “return to practice” program.

The TAP defendants have been sued in a separate class action in connection with their fraudulent pricing and marketing practices for Lupron®.

520. At a hearing in the criminal matter, which has an extensive record, United States District Court Judge William G. Young found:

This has been a gross abuse of the Medicare/Medicaid repayment system, knowing, intelligent. You have demonstrated, and it's all been confirmed in open court, and I don't want anyone forgetting about the fact that this company, not under its present management, knowingly abused the public trust in a most, and I use my words carefully, despicable way.

*United States v. TAP Pharm. Prods., Inc.*, No. CR-01-10354-WGY (D. Mass. Dec. 6, 2001).

## **2. TAP Controls the Published AWP for Its Products**

521. TAP has controlled and set the AWP for its pharmaceutical products through direct communications with industry compendia during the Class Period.

## **3. TAP's AWP Manipulation Benefited Providers at the Expense of the Class**

522. According to Criminal Information filed against several doctors and the Indictment filed against six former TAP employees and a urologist, TAP referred its practice of inflating the AWP for Lupron and the corresponding inducement to the physicians as its “Return to Practice” program.



523. At various times, TAP employees would conduct a "Business Review Meeting" with individual doctors or their staff to explain in detail how a doctor could make money by buying Lupron® and exploiting the spread.

524. TAP created sophisticated computer programs, including spreadsheets for use with physicians, to further explain how "Return to Practice" worked and how much money a physician could make from the spread. These computer programs were loaded onto laptop computers used by sales representatives and taken directly into physician's offices.

525. TAP knew and understood that, because Medicare and other insurers relied upon the Publishers to establish AWP, and because TAP could precisely control the published AWP, TAP could increase whenever they so desired the profit obtained by physicians from Plaintiffs and the Class.

#### **4. TAP Provided Free Goods and Other Incentives**

526. In addition to marketing the spread, Watson has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price.

527. For example, TAP has pled guilty to illegally conspiring with medical providers to provide free samples which would then be billed to Medicare. In an October 3, 2001, press release that referenced the guilty plea, TAP's president, Thomas Watkins, stated:

We admit that TAP provided free samples of Lupron to a number of physicians, primarily in the early to mid-1990s, with the knowledge that those physicians would seek and receive reimbursement. The billing for free samples is wrong, and it should never have happened.

528. TAP has also provided and/or arranged for many other non-public financial inducements to stimulate the sales of its drugs at the expense of Plaintiffs and the Class. Such inducements included volume discounts, rebates, off-invoice pricing, free goods, credit memos,

consulting fees, debt forgiveness and grants. All of these incentives are designed to lower the cost of the drug to the medical provider while concealing the actual cost from Plaintiffs and the Class.

529. For example, the Indictment alleges three specific instances when TAP employees offered an HMO, a urology practice and a hospital unrestricted “educational grants” of more than \$75,000 to continue their use of Lupron. It offered Tufts HMO \$65,000 in grants.

530. Another way that TAP funneled illicit payments to physicians was through the “TAP into the Future” program, which consisted of providing physicians with all-expense paid weekends at luxurious resorts. These junkets were disguised as educational or consulting programs, with all of the doctors in attendance designated as “consultants” even though the doctors who attended did not do anything that could reasonably be deemed consulting services.

531. As set forth above, TAP scheme to inflate its reported AWP and market the resulting spread to increase the market share of its drugs and its use of other “off invoice” rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

#### **5. TAP Concealed Its AWP Manipulation**

532. TAP deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread.

533. For example, TAP instructed physicians not to report the true price they paid for Lupron. According to the Indictment, a TAP Senior Marketing executive, Alan MacKenzie, advised TAP’s sales force to:

tell physicians that if doctors disclosed their invoice costs to the Medicare Program, that Program would take steps to reduce the maximum payment allowed for Lupron and thus reduce the physician’s profit for Return to Practice.

534. MacKenzie also told the sales force to caution doctors not to discuss their price discounts with other physicians and instructed TAP employees to tell urologists that:

by discussing your costs of Lupron with other physicians, you run the risk of that information getting back to HCFA. If HCFA then realizes that AWP is not a true reflection of the price, the AWP could be affected, thus lowering the amounts you may charge.

535. A presentation to TAP's sales representatives included the same statements listed above, as well as directions for the leader of the presentation, which stated:

The main point to make to physicians is that confidentiality clause is a protection for them. If word is leaked back to HCF/Medicare that the cost of Lupron is going down, they very well may take steps in reducing allowable. This tactic should help prevent physicians talking amongst themselves.

#### U. Warrick

536. Warrick has acted to inflate AWP's pursuant to the scheme identified above. The specific drugs are identified in Appendix A.

#### V. Watson

537. Watson engages in an organization-wide and deliberate scheme to inflate AWP's. Watson has stated fraudulent AWP's for all or almost all of its drugs, including: Ferrlecit, Verapamil HCL, Vinblastine Sulfate, Vincristine Sulfate, Dexamethasone, Diazepam, Gentamicin, Testosterone Ethanate, Vancomycin, Fluphenazine, Gemfibrozil, Imipramine, Nadolol, and Perphenazine. The specific drugs of Watson for which relief is sought in this case are set forth in Appendix A, and as identified below:

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
WATSON (Watson and Schein)	Ferrlecit	sodium ferric gluconate complex in sucrose injection	Iron Preparation (Blood modifier) Used for treatment of anemia in patients undergoing hemodialysis
	InfeD	iron dextran	Iron Preparation (Blood modifier); Nutritional Supplement Used for treatment of iron deficiency
		dexamethasone acetate	Hormone; Glucocorticoid Used to treat inflammatory conditions, hematologic disorders and cerebral adema
		dexamethasone sodium phosphate	Hormone; Glucocorticoid Used to treat inflammatory conditions, hematologic disorders and cerebral adema

Manufacturer	Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
		diazepam	Central Nervous System Agent Used to treat status eplipeticus and anxiety disorders. Also used as an amnesic prior to surgical procedures
		estradiol	Estrogen (Hormone) Used for treatment of menopausal symptoms and postmenopausal osteoporosis
		fluphenazine hcl	Central Nervous System Agent; Psychotherapeutic Agent Used to manage psychotic disorders
		gemfibrozil	Antilipemic Agent (Cardiovascular Agent) Used to lower cholesterol
		gentamicin sulfate	Anti-Infective Agent Used as a general antibiotic to treat serious gastrointestinal, respiratory, bone, skin and soft tissue infections
		imipramine hcl	Central Nervous System Agent; Psychotherapeutic Agent Used in the treatment of depression
		lorazepam	Central Nervous System Agent Used for treatment of anxiety disorders
		nadolol	Antihypertensive (Cardiovascular Agent) Used in the treatment of hypertension and management of angina
		perphenazine	Central Nervous System Agent; Psychotherapeutic Agent Used to manage psychotic disorders
		propanolol hcl	Beta Adrenergic Blocking Agent (Cardiovascular Agent) Used to treat hypertension
		ranitidine hcl	Histamine Receptor Antagonist (Gastrointestinal Agent) Used for treatment of duodenal ulcer, gastric ulcer, gastroesophagael disease and heartburn
		vancomycin hcl	Antibiotic Agent (Anti-Infective Agent) Used as a general antibiotic
		verapamil hcl	Calcium Channel Blocker (Cardiovascular Agent) Used in the treatment of tachyarrhythmia, angina and hypertension

**1. Watson Has Been the Target of Government Investigations**

538. In connection with its scheme to inflate AWP, Watson has been investigated by the Department of Justice, Department of Health and Human Services Office of Inspector General, and the State of California.

**2. Watson's Definition and Understanding of AWP**

539. Watson plainly recognizes that "AWP drives reimbursement." (MDLW12564) (Highly Confidential).

**3. Watson Controls the Published AWP for Its Products**

540. Watson has controlled and set the AWP for its pharmaceutical products through direct communications with industry compendia during the Class Period. In a memo, Watson states that it is faxing prices to various pricing services, but "not all pricing services received all of the prices listed on this letter. Most only received the AWP price..." The memo goes on to state that "AWP is the primary price being communicated in these faxes to establish a reference for reimbursement." (MDLW25203) (Highly Confidential).

541. A *Red Book* Product Listing Verification form asks for approval of changes to the stated AWP for Schein's (which was later acquired by Watson) Verapamil HCL, Vinblastine Sulfate and Vincristine Sulfate. A Schein executive okayed the changes and signed the *Red Book* form. (MDLW00887).

**4. Watson's AWP Manipulation Benefited Providers at the Expense of the Class**

542. When deciding where to set the price for its drug Ferlecit, Watson recognized that, in a Medicare Reimbursement Mechanism, "margin drives AWP and ASP" and that a goal of setting the price is that "profit margin at the unit level must not decrease." Watson recognizes that 20% of reimbursement is patient co-pay, which can be private insurance, Medicaid or cash. (MDLW05457-05460) (Highly Confidential).